

REMARKS

Claims 1-5, 7, 9-25, 35 are pending. Claims 26-34 are canceled without prejudice. Claim 21 is amended. Claims 36-40 are new.

Applicant appreciates the courtesy of the Examiner's telephone interview on December 2, 2008 with Applicant's undersigned representative and the Examiner's Supervisor. As required, Applicant states the subject was a discussion of a proposed Amendment in light of the art cited in the September 3, 2008 Office Action.

Applicant respectfully requests reconsideration.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-3, 14-16, and 19-20 are rejected under 35 U.S.C. §102(b) as anticipated by Brown U.S. Patent No. 6,354,729.

Applicant respectfully requests the Examiner to clarify the status of claim 35; claim 35 is not cited in the caption at ¶2, p. 2 of the Action, but is cited in the first sentence under ¶2.

Claim 1 requires that the apparatus contain "a suspendible agent suitable to be administered to a patient to diagnose or treat a medical condition", as a part of the apparatus. Brown does not recite such an agent.

The extent of Brown's medical-related disclosure is the sole statement: "The invention has application in all areas of fluid mixing and across all industries where mixing is required, for example the chemical, food, healthcare, medical, petrochemical and polymer industries." Brown is devoid of any disclosure of "a suspendible agent suitable to be administered to a patient to diagnose or treat a medical condition".

The Examiner, here and elsewhere in the rejection, relies on the fact that the claimed limitation may possibly lie within the broad disclosure of a reference, to assert that the reference discloses the limitation. This, however, is not the proper standard for anticipation, as MPEP §2112 makes clear:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but

must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<
"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

Brown discloses no more than a broad genus of potential applications (e.g. "food", "healthcare", "medical"). It is clear that Brown's disclosure is not directed to a suspendible agent suitable to be administered to a patient to diagnose or treat a medical condition, and that Brown nowhere discloses such suspendible agent. For at least this reason, Brown cannot anticipate claims 1-3, 14-16 and 35 under 35 U.S.C. §102.

During the interview on December 2, 2008, the Examiner indicated that he was interpreting the term "suspendible agent" broadly. However, the Examiner fails to point out where Brown discloses the claimed suspendible agent.

Claims 1 and 19 also recite a delivery container including a fluid reservoir holding a propellant fluid. Brown does not disclose an apparatus including a fluid reservoir holding or capable of holding a propellant fluid.

The Examiner admits that "Brown does not explicitly reference an upstream reservoir," but then states that "there is a reasonable expectation that such a reservoir was contemplated for use with the device." However, the Examiner provides no case law or patent rule citation for his "reasonable expectation" standard for anticipation under 35 USC §102. In fact, no such inference is permitted for rejections made under this section.

For a reference to anticipate a claim, it must disclose, either explicitly or inherently, every element of the claim. Since the Examiner admits that Brown does not explicitly disclose such a reservoir, the reference must inherently disclose this element in order to anticipate the claim. As set forth above, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." The Examiner has not explained, and does not assert, that a reservoir is necessarily used with Brown's device. Instead, the Examiner indicates that if Brown would reasonably use a reservoir, then it is disclosed. This is not the law.

The Examiner states, "Simply because Applicant can conceptualize a scenario where the device of Brown could be modified to be used with an upstream reservoir does not alter the implied upstream reservoir necessary so that materials may be introduced in a continual matter." The Examiner is incorrect. Brown does not disclose use of a reservoir. Further, Brown's device could be used without a reservoir, and a reservoir is not necessarily present. Because Brown clearly does not disclose, even inherently, a reservoir as claimed, the rejection should be withdrawn.

During the interview on December 2, 2008, the Examiner indicated that he was interpreting the term "reservoir" broadly. However, the Examiner fails to point out where Brown discloses the claimed reservoir.

Claims 1 and 19 recite that the suspendible agent is delivered to the exit port when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path. Brown does not disclose that causing the propellant fluid to flow through the fluid path would deliver the suspendible agent to the exit port. In fact, Brown's purpose is "distributive mixing" (col. 2 line 23). Causing propellant fluid to flow through Brown's device would mix the propellant fluid with the suspendible agent, rather than delivering the suspendible agent to the exit port. Brown explains, e.g. at col. 5 lines 37-42, that "the design illustrated is required to propel material through the channels in order to achieve the required amounts of dispersive mixing, and the pumping inefficiency desired to achieve the required residence time within the mixer."

Brown's mixer provides physical propellant force on the material to be mixed, without the need for an external propellant. Brown's mixer acts on a discrete quantity of material without the need for any continuous flow. See, e.g., Brown col. 4 lines 18-40 describing the pumping action inherent in the movement of the mixer rings. As such, it is not permissible to assume the existence of propellant fluid, because propellant fluid is not necessary for Brown's device to operate and Brown does not disclose this element. While the Examiner infers that "the propellant fluid of Brown is an upstream quantity of fluid that in part displaces the fluid temporarily disposed within the mixing/suspension apparatus," the Examiner has not shown where Brown discloses that "the introduction of new fluid to the system" propels mixed fluid to the exit port.

For at least these reasons, Brown does not anticipate claims 1-3, 14-16, and 19-20, and Applicant respectfully requests this rejection be withdrawn.

Claims 19, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by Kawasaki U.S. Patent No. 5,368,382.

The Examiner states "Though not explicit, one would reasonably expect and appreciate that the cement pump as taught by Kawasaki et al. has access to a reservoir". Again, the Examiner fails to point to any specific reservoir structure of Kawasaki et al. The Examiner admits that Kawasaki does not explicitly disclose the reservoir, but again uses a "reasonable expectation" standard, which is not the law. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The Examiner has not explained and does not assert that a reservoir is necessarily used with Kawasaki's device. Instead, the Examiner asserts that if Kawasaki would reasonably use a reservoir, then it is disclosed. Because this is not sufficient for anticipation under 35 USC §102 and because Kawasaki does not actually disclose this element as claimed, Applicant respectfully requests this rejection be withdrawn.

Kawasaki's device is not suitable for administering a suspendible contrast agent in suspension. This is a required element of claims 21 and 23-25. Kawasaki's device is specifically designed for mixing cement paste. Cement paste is not a contrast agent, as Applicant's claims require. Kawasaki has no disclosure of delivering a contrast agent and, in fact, the wall panels disclosed as being properly inserted

in a cement paste pressure feed pipe are not the proper size or material composition for the delivery of a suspendible contrast agent as claimed.

Claim 21 is amended to recite that the exit port is sized and configured for delivery of said suspendible contrast agent from said delivery container to a patient's body. Nowhere does Kawasaki disclose an outlet port that is sized and configured for delivery of a suspendible contrast agent from a delivery container to a patient's body.

For at least these reasons, Kawasaki does not anticipate claims 19, 21, and 23-25, and Applicant respectfully requests this rejection be withdrawn.

Claim 39 recites that the propellant fluid is of a different composition than the contrast agent. Applicant explains at ¶34 that the propellant fluid 33 is "any biocompatible viscous fluid and may be a diluent, such as normal saline, water, buffer, etc., for the contrast agent. The propellant fluid 33 may also be a second contrast agent having a different composition than the contrast agent 32...." Kawasaki does not disclose a propellant fluid of a different composition than the contrast agent.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as obvious over Brown.

Applicant incorporates his previous distinctions over Brown. Additionally, Brown is directed toward mixing, not to administering and agent, and Brown's device is configured for dispersive and distributive mixing. Thus, Brown is nonanalogous art. There is no reasonable expectation of success that Brown's apparatus is suitable to administer a suspendible agent to a patient to diagnose or treat a medical condition. A person of ordinary skill in the relevant art would not consider the configuration of a fluid mixer relevant to maintaining a suspendible agent in suspension and administering it to a patient. A person of ordinary skill in the art would not modify Brown's device with the elements of Applicant's claims, to arrive at Applicant's apparatus recited in claims 17-18.

For at least these reasons, Brown does not render claims 17 and 18 obvious.

Claim 22 is rejected under 35 U.S.C. 103(a) as obvious over Kawasaki, analyzed above.

Applicant incorporates his previous distinctions over Kawasaki. Additionally, claim 22 depends from claim 21, which recites an apparatus for administering a suspendible contrast agent. Kawasaki's mixer is configured for mixing cement. Thus, Kawasaki is non-analogous art. There is no reasonable expectation of success that Kawasaki's apparatus would administer a suspendible contrast agent in suspension. A person of ordinary skill in the relevant art would not consider the configuration of a cement mixer relevant to maintaining a suspendible contrast agent in suspension. A person of ordinary skill in the art would not modify Kawasaki's device with the dimensions claimed, to arrive at Applicant's apparatus recited in claim 22.

For at least these reasons, Kawasaki does not render claim 22 obvious.

Claims 4-13 are rejected under 35 U.S.C. 103(a) as obvious over Hodan U.S. Patent No. 5,137,369 in view of Hirose U.S. Patent No. 4,869,849.

Hodan is directed to a static mixing device for homogenizing molten polymer. Thus, Hodan is nonanalogous art. A person of ordinary skill in the art would not look to Hodan's device, for mixing molten polymer, to administer a suspendible agent in suspension as claimed. A person of ordinary skill would not modify Hodan to arrive at the claimed device.

The Examiner presents Hodan's inlet 11 as the claimed fluid reservoir. However, Hodan's inlet 11 is not a fluid reservoir; rather, it is a fluid inlet. Hodan does not teach, suggest, or motivate a fluid reservoir, nor does Hodan teach, suggest, or motivate any component that acts as a fluid reservoir as claimed.

Hodan also does not teach, suggest, or motivate a delivery mechanism operative for causing propellant fluid to flow through the fluid path, because Hodan does not teach propellant fluid at all. Hodan does not state the mechanism by which molten polymer enters the static mixer, and the Examiner's explanation ("in the instant case the pressure of introduced fluid in combination with gravity") has no support in Hodan's specification.

Claim 4 is amended to recite that a side wall of the delivery container at least partially bounds the fluid reservoir and at least partially bounds the fluid path at least partially defined by the suspension apparatus. Hodan does not teach, suggest, or motivate such an arrangement.

Hirose does not cure Hodan's deficiencies. Thus, for at least these reasons, Hodan in view of Hirose do not render claims 4-13 obvious. Applicant respectfully requests this rejection be withdrawn.

New claim 39 depends from claim 4, and recites that the apparatus is in the form of a syringe, the delivery container comprising a barrel of the syringe, the suspension apparatus and reservoir located in the barrel. This arrangement is described, for example, at Applicant's ¶124. Hodan and Hirose, alone or in combination, fail to disclose or fairly suggest this claimed arrangement.

CONCLUSION

The application is believed to be in complete condition for allowance with no fees due. If fees are deemed necessary, the Office is authorized to charge them to Deposit Account 20-0809.

The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,

THOMPSON HINE LLP

/Christopher W. Elswick/

Christopher W. Elswick

Reg. No. 56,673

Intellectual Property Group
P.O. Box 8801
Dayton OH 45402
513 352 6589
710832